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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,419	01/25/2002	Craig L. Schmidt	P-7586.01	1349
27581	7590	06/06/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,419

Applicant(s)

SCHMIDT ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2005 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 18-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6,456,883. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims inclusion of a control circuit to control operation of the device and to obtain physiological data would have been seen as an inherent component in the system defined in the '883 patent. All implantable medical devices require control circuitry to function. Furthermore, the recitation of a first power source and a second power source is merely a broader description of the more limiting main power source and the supplemental power source set forth in the patent.

The use of batteries as a power source for the implant would have also been considered blatantly obvious considering the inherent portable, self-contained nature of the battery. The particular battery chemistry would have been considered a matter of obvious design as discussed below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 18, 19, 21, 28 and 30 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Torgerson et al. (Pat. No. 6,456,883).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 102/103

6. Claims 23-27 and 29 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Torgerson et al..

Regarding claim 23, the examiner in rejecting this claim will consider the first power source to be represented by the supplemental power source of Torgerson et al. and the second power source to be represented by the main power source of Torgerson et al.. The supplemental power source must be coupled to the control circuit to enable data to be transmitted to an external unit when the main power source is switched out,

and the main power source must be coupled to the communications circuit during normal operation prior to depletion. Switch 50 can therefore be said to couple the first power source to the communication circuit upon the occurrence of a first predetermined event (i.e., when the second/main power source is depleted). In any event, even if one considers the first power source to equate to the main power source and the second power source to equate to the supplemental power source, Torgerson et al. disclose that the main power source may be rechargeable (see col. 10, lines 10-15). It would have therefore been obvious to switch back to the main power source from the supplemental power source once the main power source was adequately recharged (a first predetermined event), since the supplemental power source was never intended for long term use.

The limitations expressed in claims 24 and 25 are clearly anticipated.

Regarding claims 26 and 27, the switch 50 couples the second power source to the control circuit when the remaining power of the first power source falls below a threshold (see Fig. 3).

The rejection of claim 29 parallels the rejection of like limitations above.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over Torgerson et al. (Pat. No. 6,456,883).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an

invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Regarding claims 20 and 22, while Torgerson et al. do not elaborate on the particular type of battery chemistry employed, the examiner takes Official Notice that the various chemistries listed are all old and well-known to the medical implant artisan. Torgerson et al. further teach that rechargeable batteries may be utilized in the construction of the invention. Lithium-ion and nickel/metal hydride batteries are notoriously well-known rechargeable batteries. The applicants fail to express any criticality in one arrangement over the other, and in fact state that it would be appreciated that the batteries may take any known form of construction, or similar type chemistries (page 23). The decision to employ any one of the battery chemistries listed in claims 20 and 22 would have therefore been considered a matter of obvious design by those of ordinary skill in the medical implant art, with the choice dependent upon the particular application at hand.

9. Claims 18, 19, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilz et al. (Pat. No. 6,044,295).

Regarding claims 18 and 28, Pilz et al. disclose an implantable medical device comprising a control circuit 6 to control the operation of the implantable medical device, a communication circuit 23, 24 coupled to the control circuit to transmit data to an external device, a first power source 2 positioned within the device and coupled to the control circuit (see Fig. 1) to provide power to the control circuit, and a second power source 1 positioned within the device and coupled to the communication circuit.

Although Pilz et al. are silent as to the use of the control circuit for obtaining physiological data and transmitting this collected data to an external device via the communication circuit, the examiner takes Official Notice that it is old and well-known in the cardiac treatment arts for implants to obtain physiological data and store it for later transmission to an external device so as to permit concomitant analysis by the patient's physician, thus enabling more effective treatment. Such a feature is considered an essential function for any medical therapy implant.

Regarding the recitation concerning the coupling of a second power source to the communication circuit, it is inherent that the communication circuit needs power to transmit. In the case where the depleted first power source is switched out of the circuit, the second power source supplies all the necessary current for the proper functioning of the device (see col. 3, lines 4-20). One can also argue that since the intent of the second power source of Pilz et al. is to supply high current pulses when needed, and since the telemetry of data as indicated by the applicant typically involves high current pulses (see page 23 of the present invention, first full paragraph), it would have been obvious to the implantable medical device designer to utilize the second power source for providing power to the communication circuit when needed.

Regarding claim 30, note col. 4, lines 1-18.

10. Claims 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (Pat. No. 4,096,866).

Regarding claims 18 and 28, Fischell discloses a control circuit 44, a first power source (either element 13 or 43), and a second power source (the other of elements 13 or 43). Although Fischell does not discuss the use of a communication circuit for transmitting obtained physiological data to an external device, the examiner takes Official Notice that such circuits are old and well-known in the medical implant arts (see the parallel argument made above on this issue with respect to the Pilz et al. reference). To couple power source 43 (or 13) to such a communication circuit in order to provide it with the requisite power for transmission of data would have been considered inherently necessary, or in the least, blatantly obvious by any artisan of ordinary skill.

Regarding claim 20, note the rejection of said claim above under paragraph 8. Similar comments apply here as well.

Claims not specifically discussed are considered either clearly anticipated, or are rejected in a parallel manner to that which has already been discussed above.

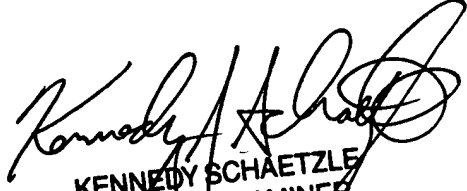
Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
June 1, 2005



KENNEDY SCHAETZLE
PRIMARY EXAMINER